

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
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THIS DOCUMENT RELATES TO:)	MDL No. 2419
<hr/>		Dkt. No 1:13-md-2419 (RWZ)
The cases listed in Exhibit A to the)	Leave to file granted at
Saint Thomas Entities' and Ascension)	May 13, 2014 Status Conference
Parties' Motion to Dismiss)	
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**REPLY IN SUPPORT OF MOTION TO DISMISS FOR FAILURE TO COMPLY WITH
TENNESSEE HEALTH CARE LIABILITY ACT**

In their Motion to Dismiss,¹ the Saint Thomas Entities and Ascension Parties demonstrated that the Tennessee Plaintiffs have failed to satisfy the pre-suit notice and good faith certificate requirements of the Health Care Liability Act. In Response,² the Tennessee Plaintiffs claim that the pre-suit notice and good faith certification requirements are not applicable to products liability claims; their “technical” noncompliance should be excused; and they should be permitted to cure any defects through pleadings amendments. None of these grounds is tenable.

First, the Tennessee Plaintiffs’ claims against the Saint Thomas Entities and Ascension Parties are governed exclusively by the Health Care Liability Act, and, in any event, neither these Defendants nor the Tennessee Clinic Defendants are “sellers” under the Products Liability Act.³ Second, the Tennessee Supreme Court has held that the 60-day pre-suit notice and the good faith certificate requirements of the Health Care Liability Act are not merely “technical deficiencies,” but mandatory requirements that cannot be satisfied through substantial

¹ *Motion to Dismiss for Failure to Comply with the Tennessee Health Care Liability Act* and *Memorandum in Support* (Docket ##779, 780) (respectively, “Motion” and “Memo”). For consistency, the Saint Thomas Entities and Ascension Parties will continue to use the terms they defined in their Memo.

² *Plaintiffs’ Steering Committee’s Response in Opposition to Motion to Dismiss Based on Failure to Comply with Tennessee Healthcare Liability Act Filed by the Saint Thomas Entities* (Docket #1115) (“Response”).

³ Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.* (“Products Liability Act”).

compliance. Finally, the Tennessee Plaintiffs cannot use the federal rule on alternative pleading to create a cause of action that is otherwise not cognizable under Tennessee law.

ARGUMENT

I. The Tennessee Plaintiffs' Exclusive Remedy Is Under the Health Care Liability Act

Under the Tennessee Civil Justice Act of 2011, any suit filed in Tennessee after October 2011 against a health care provider claiming injury “*related to* the provision of, or failure to provide, health care services to a person, *regardless of the theory of liability on which the action is based*,” is a “health care liability action,” which must comply with the Health Care Liability Act’s requirements. TENN. CODE ANN. § 29-26-101(a)(1) (emphasis added). Indeed, “[a]ny such civil action or claim is subject to this part *regardless of any other claims, causes of action, or theories of liability alleged in the complaint.*” *Id.* § 29-26-101(c) (emphasis added).

Legislative history confirms that the General Assembly intended the Act to be the sole cause of action for claims against health care providers. Senator Mark Norris, the sponsor of the bill, explained: “It is advantageous in the minds of some plaintiffs to keep it out from under the health care provider statutes, make a cause of action look like something it isn’t at its core, and so you spend most of your time at the outset trying to define what the cause of action is. We’re hopeful that this statute will obviate some of that and reduce some of that time and expense.”⁴

In attempting to evade the Act and its procedural requirements, the Tennessee Plaintiffs claim that the one-year statute of limitations in the Products Liability Act and the 60-day pre-suit notice requirement in the Health Care Liability Act constitute “incongruent temporal requirements” and create a “Catch 22,” because a plaintiff must file a products liability claim within one year of the date the plaintiff discovers or should have discovered that he or she was injured, yet cannot file a health care liability claim until 60 days after providing pre-suit notice.

⁴ Remarks of Tennessee General Assembly, 34th Legis. Sess., Senate (May 12, 2011), available at: http://tnga.granicus.com/MediaPlayer.php?view_id=196&clip_id=4266&meta_id=81904 (discussion beginning at 1:08:21) (last viewed on June 2, 2014).

The “temporal requirements” of the Products Liability Act and the Health Care Liability Act are only incongruent if it is assumed that a plaintiff could assert both a products liability claim and a health care liability claim against the same defendant. But the General Assembly did not intend such a result. Rather, as the statute clearly provides, the Health Care Liability Act is the sole remedy for a plaintiff who seeks to assert a claim related to the provision of health care services.

Nor have the Tennessee Plaintiffs alleged that the Saint Thomas Entities or Ascension Parties are “sellers” under the Products Liability Act. Instead, they have alleged: “As part of this medical treatment, the ***Clinic Related Defendants*** administered NECC contaminated drugs, and/or NECC drugs suspected to be contaminated, to the Plaintiffs.” Master Complaint ¶ 153 (emphasis added).⁵ Further, the Tennessee Clinic Defendants—for whom Plaintiffs claim the Saint Thomas Entities and Ascension Parties are vicariously liable—are not sellers under the Products Liability Act as a matter of law.⁶ The Products Liability Act defines “seller” as a “retailer, wholesaler, or distributor, and means any individual or entity ***engaged in the business of selling a product.***” TENN. CODE ANN. § 29-28-102(7) (emphasis added). Providers of professional services like these Defendants, are not “sellers” of the tangible products used in the course of providing that professional service. *See Parker v. Warren*, 503 S.W.2d 938 (Tenn. Ct. App. 1973) (finding carpenters not liable as sellers of defective lumber); *Delta Ref’g Co. v. Procon, Inc.*, 552 S.W.2d 387 (Tenn. Ct. App. 1976) (general contractor who installed pump not strictly liable as seller of pump where pump was manufactured by third party).

For example, in *Pass v. Shelby Aviation, Inc.*, the Court of Appeals found that a contract for inspection and repair of the plaintiff’s aircraft, under which the defendant replaced two “attach point brackets” on the aircraft’s rear wings, was predominantly a services contract not

⁵ The Master Complaint contains a list of the entities that constitute “Clinic Related Defendants”—the Saint Thomas Entities and the Ascension Parties are not included on that list.

⁶ The Saint Thomas Entities and Ascension Parties incorporate by reference the arguments made by the Tennessee Clinic Defendants demonstrating that they are not “sellers” under the Products Liability Act.

covered by the Products Liability Act. No. W1999-00018-COA-R9-CV, 2000 WL 388775, at *6 (Tenn. Ct. App. Apr. 13, 2000). The plaintiff had sought out the defendant primarily for a service—an annual inspection—of the aircraft; the invoice emphasized repair and inspection services; and the charges for service and labor amounted to more than 60% of the parties' contract. *Id.* Under these circumstances, the “final product” the plaintiff had “bargained to receive” was predominantly a service, *id.*, and any sale of goods was only incidentally involved. *Id.* at *6. Here too, the relationship between the Tennessee Plaintiffs, STOPNC, and Howell Allen Clinic was predominantly a transaction for the provision of healthcare services—not the purchase of methylprednisolone (“MPA”). Administration of MPA was part of their medical treatment, so the Tennessee Plaintiffs cannot state a claim for products liability against the clinic and, accordingly, cannot hold the Saint Thomas Entities or Ascension Parties vicariously liable.

II. Substantial Compliance Is Not Enough

When requirements of the Health Care Liability Act are mandatory—as are pre-suit notice and the good faith certification—the failure to satisfy those requirements warrants dismissal of a complaint. Memo at 5, 12. These mandatory provisions cannot be satisfied through substantial compliance, and a health care provider defendant does not need to show prejudice. *Myers v. Amisub (SFH), Inc.*, 382 S.W.3d 300, 309 (Tenn. 2012) (pre-suit notice requirement is “mandatory, not directory,” and strict, rather than substantial compliance, was required in order to maintain a medical malpractice action);⁷ *see also* Memo at 5-6, 12-13.

Plaintiffs assert that *Thurmond v. Mid-Cumberland Infectious Disease Consultants*, No. M2012-02270-SC-R11-CV, 2014 WL 1632183 (Tenn. Apr. 24, 2014), lowered the standard to

⁷ TENN. CODE ANN. § 29-26-121(b) excuses compliance with the 60-day pre-suit notice requirement only for “extraordinary cause.” “Extraordinary” is commonly defined as ‘going far beyond the ordinary degree, measure, limit, etc.; very unusual; exceptional; remarkable.’ *Myers*, 382 S.W.3d at 310-11 (quoting WEBSTER'S NEW WORLD DICTIONARY OF THE AMERICAN LANGUAGE 516 (1966)). Plaintiffs have not alleged that the failure to file the 60-day pre-suit notice was the result of any extraordinary cause.

substantial compliance. *See* Response at 11–12.⁸ But the only issue before the *Thurmond* court was whether the “statutory requirement of an affidavit of the person who sent pre-suit notice by certified mail may be satisfied by substantial compliance”—*not* “an allegation that Plaintiff failed to provide pre-suit notice as required by [S]ection 29-26-121(a)(1) or that the content of the notice provided was deficient” 2014 WL 1632183, at *1, 5. *Myers* thus supplies the rule of law requiring strict compliance for the pre-suit notice requirement, which cannot be met here.

III. These Defects Cannot Be Cured by Amending or Alternative Pleadings

Contrary to the Tennessee Plaintiffs’ argument, their right to plead in the alternative under Federal Rule of Civil Procedure 8 does not permit them to circumvent the Health Care Liability Act. Nor do they cite any authority for this novel argument. Their reliance on *Hanna v. Plumer*, 380 U.S. 460 (1965), and *Shady Grove Orthopedic Assocs. v. Allstate Ins. Co.*, 559 U.S. 393 (2010), is misplaced. Both cases involved claims that state procedural laws trumped the federal rules. But the Tennessee Health Care Liability Act and Products Liability Act are substantive laws, conferring substantive rights, so are not implicated by these decisions. *See* 28 U.S.C. § 2072(b) (explaining that federal rules cannot “abridge, enlarge or modify any substantive right”); *see also In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367, 409 (D. Mass. 2013) (holding that the Illinois statute at issue conferred “substantive rights upon” state citizens and thus could not be preempted by a federal procedural rule because to do so would be “an application of a federal rule that effectively abridges, enlarges or modifies a state-created right or remedy,” which is prohibited by the Rules Enabling Act).

⁸ Tennessee courts interpreting the Health Care Liability Act have drawn a distinction between the pre-suit notice filing requirement, and the content requirements, which may be subject to a substantial compliance standard. *See Chambers ex rel. Chambers v. Bradley Co.*, No. E2013-01064-COA-R10-CV, 2014 WL 1266101, at *5–6 (Tenn. Ct. App. Mar. 28, 2014) (applying a substantial compliance standard to satisfy content requirements); *Potter v. Perrigan*, No. E2013-01442-COAR3-CV, 2014 WL 1260609, at *4 (Tenn. Ct. App. Mar. 27, 2014) (describing *Stevens v. Hickman Comm. Health Care Servs., Inc.*, 418 S.W.3d 547 (Tenn. 2013), as requiring only “substantial compliance” with content requirements). In contrast, the Tennessee Supreme Court has specifically held that the pre-suit notice and certificate of good faith filing requirements may not be satisfied by mere substantial compliance. *See Myers*, 382 S.W.3d at 310 (“Because [the requirements that pre-suit notice be given and that a certificate of good faith be filed] are mandatory, they are not subject to satisfaction by substantial compliance.”).

CONCLUSION AND PRAYER

For these reasons, and the ones set forth in their Motion and Memo, the Saint Thomas Entities and Ascension Parties request that the Court grant their motion to dismiss.

Respectfully submitted,

SAINT THOMAS WEST HOSPITAL,
FORMERLY KNOWN AS ST. THOMAS
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SAINT THOMAS HEALTH, ASCENSION
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By its attorneys,

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CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 9th day of June, 2014

/s/ Sarah Kelly
SARAH KELLY